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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HEALTH SCIENCE FUNDING, LLC, Plaintiff, v. THE UNITED STATES FOOD & DRUG ADMINISTRATION and MARGARET A. HAMBURG, in her official capacity as Commissioner of the FDA, Defendants.	HON. CLAIRE C. CECCHI Civil Action No. 2:13-cv-03663-CCC-JAD **MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION** Motion Date: Aug. 5, 2013

Table of Contents

Cases

Statutes

Other Authorities

Regulations

INTRODUCTION

The United States Food and Drug Administration ("FDA") and Margaret Hamburg, in her official capacity as Commissioner of FDA (collectively, "Defendants"), submit this memorandum in support of their motion to dismiss plaintiff's complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) and in opposition to plaintiff's motion for a preliminary injunction.

Plaintiff seeks injunctive and declaratory relief related to its product, Prastera. Prastera contains dehydroepiandrosterone ("DHEA"), a hormone that is made by the human body and is commonly sold over the counter as a dietary supplement. Prastera's labeling states that it is indicated "in female patients with mild to moderate, active" lupus "to restore [DHEA] serum . . . to levels typical of women without [lupus]." Pl.'s Decl. Ex. 17. The labeling further states that the product "was associated with reduced risk of auto-immune flare." *Id.*

Rather than putting forth the expense and effort of submitting a new drug application ("NDA") and undergoing premarket review by FDA in order to legally offer its product for sale as a drug, plaintiff seeks a judicial declaration that its product is a "medical food." Plaintiff proceeds with this strategy without a finding from FDA or any other credible scientific source that lupus even has distinctive nutritional requirements, or that lupus is a disease for which dietary management would be appropriate, each of which is required for its product to be considered a medical food.

The Orphan Drug Act defines a "medical food" as "food . . . intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." 21 U.S.C. § 360ee(b)(3). FDA has long construed this definition narrowly to avoid the precise result that

plaintiff seeks: the ability to sell a product with labeling indicating its intended use to treat or mitigate a particular disease or condition (such as reducing the risk of flares) without actually having to prove that it is safe and effective (as plaintiff would be required to do through an NDA) prior to offering the product for sale. Although the product's labeling contains a disclaimer stating that "Prastera does not cure, treat, mitigate or prevent [lupus]," plaintiff removes any doubt as to its intended use as it argues to this Court that its product is capable of "sav[ing] four innocent women's lives" each day. Compl. ¶ 64.

Common examples of legitimate medical foods that meet the statutory definition include nutritional formulas to manage metabolic disorders, such as foods that are free of phenylalanine, a commonly occurring substance in food that is toxic to people with phenylketonuria. But not all diseases or conditions have such recognized distinctive nutritional requirements, and FDA has carefully scrutinized claims for medical foods to ensure that a manufacturer's claim that its product is intended for the dietary management of a disease or condition has a credible and recognized scientific basis.

Moreover, plaintiff lacks jurisdiction to bring this action because the informal actions FDA has taken in this case do not amount to either enforcement action or final agency action with respect to plaintiff—FDA has not even taken the basic, preliminary step of sending plaintiff a warning letter. Plaintiff apparently fears enforcement action because it informally sought a determination from the agency in September 2012 that its product was a medical food and did not receive a favorable response. But FDA has neither the legal authority nor the capacity to perform routine premarket reviews for proposed medical food products and their labeling, and it has not made any final decision about the status of plaintiff's product. Plaintiff lacks standing to sue and its claims are not ripe for adjudication at this time.

In addition, under settled law, plaintiff may not bring this preenforcement challenge to an action that FDA could conceivably bring in the future. Further, plaintiff also fails to state a valid claim under the Administrative Procedure Act ("APA"), and its request that this Court usurp FDA's authority in the absence of any cognizable cause of action is unfounded.

Finally, plaintiff has failed to demonstrate that it meets the requirements for obtaining preliminary relief. Plaintiff is not likely to succeed on the merits, nor has it established any harm to itself or that the balance of the harms favors such drastic relief. Accordingly, this Court should deny plaintiff's motion for a preliminary injunction and dismiss its Complaint.

BACKGROUND

I. Statutory and Regulatory Background

Due to the relatively uncommon manner in which plaintiff seeks to offer its product for sale, it is helpful to briefly summarize other pathways by which similar products may be legally offered for sale.

A. Dietary Supplements

DHEA is widely available in dietary supplement products.[1] The Dietary Supplement Health and Education Act of 1994 defines a dietary supplement product as:

> a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an amino acid, an herb or other botanical; or a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, a metabolite, a constituent, an extract, or a combination of any ingredient described above; and intended for ingestion in the form of a capsule, powder, softgel, or gelcap, and not represented as a conventional food or as a sole item of a meal or the diet

21 U.S.C. § 321(ff).

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[1] *See, e.g.*, NIH Dietary Supplement Label Database, *available at* http://dsld.nlm.nih.gov/dsld/index.jsp. Of note, DHEA is reportedly banned by the Olympics, the World Anti-Doping Agency, and several other athletic associations. *See* Anne E. Kornblut and Duff Wilson, How One Pill Escaped the List of Controlled Steroids, NY Times (Apr. 17, 2005), *available at* http://www.nytimes.com/2005/04/17/national/17steroid.html?pagewanted=1&_r=0.

As relevant here, the labeling of dietary supplements (and conventional foods) may bear certain "health claims," which describe a relationship between a food, food component, or dietary supplement ingredient, and *reducing the risk* of getting a disease or health-related condition.[2] By contrast, after a patient actually develops a disease or health-related condition, any claims that a product is intended to *treat* that condition would make that product a drug; it would no longer be considered a dietary supplement.

Dietary supplements may also make certain structure-function claims that they are intended to affect the structure or function of the human body, with appropriate disclaimers that FDA has not evaluated the claim, and that "this product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 343(r)(6). Dietary supplements may also make a claim about a benefit related to a classical nutrient deficiency disease, if they also disclose the prevalence of the disease in the United States.[3] Dietary supplement manufacturers are subject to current good manufacturing practice requirements at 21 C.F.R. part 111.

B. Drugs

As relevant here, a drug is defined as: (1) an article "recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States or official National Formulary, or any supplement to any of them; (2) an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease"; or (3) an article "(other than food) intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1). If a

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[2] *See* Claims That Can Be Made for Conventional Foods and Dietary Supplements (Sept. 2003), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm.

[3] *See* Guidance for Industry: Frequently Asked Questions About Medical Foods (Rev. May 2007), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/ucm054048.htm.

sponsor wishes to market a drug, it must submit an application for approval unless the product meets specific exceptions not relevant here. 21 U.S.C. § 355(a).[4] To obtain approval, a sponsor must show, among other things, substantial evidence that the drug is effective, defined as:

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof

21 U.S.C. § 355(d)(7).

C. Medical Foods

Congress defined a "medical food" as part of the Orphan Drug Act Amendments of 1988:

> [A] food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

21 U.S.C. § 360ee(b)(3). FDA has further clarified the statutory definition of "medical food" by regulation, exempting products from certain nutrition labeling requirements if:

> (i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
>
> (ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or *who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone*;

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[4] For example, certain drugs may be marketed over-the-counter without FDA prior approval if they meet monograph requirements; it is also possible that a drug could be grandfathered. *See generally* Compliance Policy Guide, Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs (Sept. 2011), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074382.htm.

> (iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
>
> (iv) It is intended to be used under medical supervision; and
>
> (v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

21 C.F.R. § 101.9(j)(8) (emphasis added).

After FDA promulgated this regulation through notice and comment rulemaking, it issued an advanced notice of proposed rulemaking ("ANPRM") in 1996 further explaining its thinking for medical foods, emphasizing the following principles when evaluating these products:

> 1. A product marketed for use as a medical food in the dietary management of a disease or condition should have characteristics that are based on scientifically validated distinctive nutritional requirements of the disease or condition.
>
> 2. There should be a scientific basis for the formulation of the product and the claims made for the product.
>
> 3. There should be sound, scientifically defensible evidence that the product does what it claims to do.

61 Fed. Reg. 60661 (November 29, 1996), at 60666-67. FDA further emphasized that efficacy claims would need to be supported by a "strong standard of substantiation," stating that its "preliminary view is that the scientific standard contained in the statutory medical food definition may require some of the same types of data for medical foods as are needed to support drug claims (e.g., data from clinical investigations)." *Id.* at 60671. FDA did not view the physician as independently determining whether a product is a medical food, but rather as relying upon the labeling when evaluating the product for patient care:

> A physician relies on the claims made for medical foods on their labels and in their labeling as a significant factor in deciding whether to use a particular medical food in the clinical management of a patient. Thus, it is essential that the claims made for such a product present an accurate interpretation of the scientific evidence concerning the usefulness of that product or specific formulation. It is critical for the safe and appropriate use of the medical food that the claims made for it are accurate and unbiased, and that they are based on a critical evaluation of

> the science available to the manufacturer. The need for physicians and patients to have confidence that any claim that a product is a medical food formulated for the specific dietary management of a disease or condition requires that a strong standard of substantiation be in place. A strong standard of substantiation would be one that requires that all pertinent data be considered in the formulation of the product and in the development of any claims about its use.

Id. at 60669-70.

More recently, FDA has issued revised guidance expressing its narrow construction of the definition of "medical foods":[5]

> Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet *distinctive nutritional requirements* of a disease or condition, *used under medical supervision* and *intended for the specific dietary management of a disease or condition*. The term "medical foods" does not pertain to all foods fed to sick patients.

Id. (emphases added).

Unlike drugs, medical foods do not undergo FDA premarket review. Medical foods are subject to certain other requirements pertaining to foods. Any component of a medical food must be (1) a food additive used in accordance with the agency's food additive regulations (21 C.F.R. § 172); (2) a color additive used in accordance with the agency's color additive regulations (21 C.F.R. §§ 73, 74); (3) a substance that is generally recognized, by qualified experts, to be safe under the conditions of its intended use (21 U.S.C. § 321(s), 21 C.F.R. § 170.30); or (4) a substance that is authorized by a prior sanction issued by FDA (21 C.F.R. § 170.3(e)(l)). Medical foods that contain unapproved food additives are deemed unsafe,

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[5] *See* Guidance for Industry: Frequently Asked Questions About Medical Foods (Rev. May 2007), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/MedicalFoods/ucm054048.htm (citing Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrition Content Revision proposed rule (56 Fed. Reg. 60366 at 60377, Nov. 27, 1991)).

21 U.S.C. § 348(a), and adulterated under 21 U.S.C. § 342(a)(2)(C). DHEA has never been approved as a food additive for any use in food, nor is FDA aware of any basis for the general recognition of safety based either on scientific procedures or common use in food prior to January 1, 1958. In addition, among other requirements, medical foods must be prepared, packed, and held in compliance with current good manufacturing practice requirements applicable to foods. 21 C.F.R. pt. 110.[6]

D. Warning Letters and FDA Enforcement Actions

When FDA becomes aware that a regulated entity is violating the Federal Food, Drug, and Cosmetic Act ("FDCA"), the agency may issue a "Warning Letter" to, among other things, give the company an opportunity to take voluntary corrective action before any enforcement is undertaken. FDA describes Warning Letters as "the agency's principal means of achieving prompt voluntary compliance with the [FDCA]." *Regulatory Procedures Manual*, ch. 4, § 4-1-1 (2011), *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProcedures Manual/ucm176860.htm. Warning Letters are "informal and advisory." *Id.* As such, a Warning Letter "communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued." *Id.*

By contrast, FDA enforcement actions are final agency actions that may be challenged in the context of that specific action, when the facts and legal basis of the action are developed. As relevant here, FDA may: (1) initiate a seizure under 21 U.S.C. § 334 against adulterated or

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[6] *See* Guidance for Industry: Frequently Asked Questions About Medical Foods (Rev. May 2007), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/MedicalFoods/ucm054048.htm.

misbranded products, *id.* § 6-1; or (2) seek to enjoin sales of adulterated or misbranded articles under 21 U.S.C. § 332, *id.* § 6-2.

II. Factual Background

A sponsor other than plaintiff has submitted an NDA seeking approval of a product containing DHEA to treat lupus, but it has not been approved.[7] Plaintiff now offers Prastera for sale as a medical food. The labeling of plaintiff's product describes it as "200mg oral softgel capsules supplied in a convenience package with ibuprofen oral tablets 300mg." Pl.'s Decl. Ex. 17 at 1.[8]

Plaintiff requested that FDA assess whether its product is a medical food, but FDA does not conduct such premarket reviews for medical foods because it does not have the legal authority or the resources to do so. FDA responded to plaintiff as a courtesy, noting that it does not conduct such reviews and that "we do not see how this product meets the burden of the statutory definition for medical foods." *See* Letter from Benson Silverman to Mark Kohl (Oct. 17, 2012) (Pl.'s Decl. Ex 19). FDA also noted that "we have some serious questions and concerns related to the proposed marketing of Prastera as a medical food." *Id.* Later, plaintiff's counsel sought clarification and met with FDA officials on February 25, 2013. Pl.'s Decl. Ex. 23. Plaintiff alleges that FDA officials threatened to seize its product at this meeting. Pl.'s Mem. at 10. There are no official FDA minutes of this meeting.

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[7] *See, e.g.*, Genelabs Receives Approvable Letter From FDA (Aug. 29, 2002), *available at* http://www.genelabs.com/pressReleases/082902.html. This brief refers only to publicly-available information. *See* 21 C.F.R. § 314.430.

[8] By contrast, the website promoting Prastera states that it is packaged with a prescription-strength anti-acne topical gel, but does not identify that medicine. *See* http://www.prastera.com.

Plaintiff brought this suit on June 13, 2013, and filed a motion for a preliminary injunction one day later. Plaintiff seeks a declaration that its product is a medical food and an order enjoining FDA from taking any enforcement action against Prastera.

ARGUMENT

III. Plaintiff's Complaint Should Be Dismissed

Federal judicial power is limited by Article III of the Constitution to the resolution of "cases" and "controversies." *See, e.g.*, *Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 471 (1982). To invoke federal court jurisdiction, a party must establish the existence of a "justiciable controversy" with the adverse party—one that is "definite and concrete, touching the legal relations of parties having adverse legal interests." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). The party invoking the jurisdiction of a federal court bears the burden of establishing that the court has jurisdiction. *S.R.P. v. United States*, 676 F.3d 329, 343 (3d Cir. 2012).

To state a claim upon which relief may be granted, the plaintiff must allege "any set of facts consistent with the allegations," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 (2007), that "possess enough heft to 'sho[w] that the pleader is entitled to relief,'" *id.* at 557 (citations omitted). Upon review of a motion to dismiss for failure to state a claim under Rule 12(b)(6), the court must treat the complaint's factual allegations as true and draw all reasonable inferences in the plaintiff's favor. *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 84 (3d Cir. 2011). The court need not accept as true legal conclusions cast as factual allegations or inferences unsupported by facts set out in the complaint. *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007).

A. Plaintiff's Complaint Should be Dismissed Due to a Lack of Standing

"Under Article III of the Constitution, federal courts may adjudicate only actual, ongoing cases or controversies. To invoke the jurisdiction of a federal court, a litigant must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision." *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477 (1990) (citations omitted); *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 492 (2009). "The party invoking federal jurisdiction bears the burden of establishing these elements." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992).

The "actual injury" must be "concrete in both a qualitative and temporal sense." *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990). The injury must be "distinct and palpable" and "actual or imminent," not "conjectural" or "hypothetical." *Id.* (citations omitted); *see also Defenders of Wildlife*, 504 U.S. at 560. To establish injury in fact, a "plaintiff must allege that he has been or will in fact be perceptibly harmed by the challenged agency action, not that he can imagine circumstances in which he could be affected by the agency's action." *United States v. SCRAP*, 412 U.S. 669, 688-89 (1973); *see also McNair v. Synapse Grp. Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) (requiring showing that plaintiff is "likely to suffer future injury" from defendant's conduct). In a declaratory judgment action, the court must assess whether the facts alleged, under all the circumstances, "show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

Here, plaintiff has not alleged an injury sufficiently imminent and concrete to establish Article III standing. Plaintiff states that FDA "verbally threaten[ed] Plaintiff with enforcement action" at the 2013 meeting, but acknowledges that "FDA has for nearly a year pointedly avoided taking any." Compl. ¶¶ 3-4. Any such informal statement made at meeting, even if

true, does not constitute a final agency action subject to judicial review. *See* 21 C.F.R. § 10.85(k) ("A statement or advice given by an FDA employee orally, or given in writing . . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.").

As FDA has made clear, Warning Letters are "informal and advisory," and are intended to give recipients the opportunity to take voluntary corrective action.[9] Such letters "communicate[] the agency's position on a matter," but do not "commit FDA to taking enforcement action." *Id.* For this reason, courts have repeatedly and consistently held that such letters are not subject to judicial review. *See, e.g.*, *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944-945 (D.C. Cir. 2012); *Mobil Expl. & Prod. U.S., Inc. v. Dep't of Interior*, 180 F.3d 1192, 1198-99 (10th Cir. 1999) (agency letter not final where it served to "initiate further proceedings" and "was not the consummation of the agency's decisionmaking process"); *Dietary Suppl. Coal., Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992) (holding that FDA regulatory letters do not constitute final agency action); *Am. Fed'n of Gov't Emps. v. O'Connor*, 747 F.2d 748, 752-53 (D.C. Cir. 1984) (dismissing claims challenging agency letter because it "binds neither the public nor any agency or officer of government. No precedent known to us sanctions court review of such nonbinding advisory expositions."); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (no jurisdiction to review action challenging FDA Warning Letters because "such letters do not commit the FDA to enforcement

[9] *See* FDA *Regulatory Procedures Manual*, ch. 4, § 4-1-1 (2011) *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176860.htm.

action").[10] Because warning letters themselves are not final agency action, plaintiff would not be able to sue FDA based on such a letter even if FDA had sent one to *plaintiff* (which FDA has not). Plaintiff's attempt to bootstrap jurisdiction from warning letters that FDA has sent to *other* manufacturers is unavailing. Compl. ¶¶ 37-38.

Nor can plaintiff establish injury in fact by speculating that "FDA's threat of seizure chills Plaintiff's willingness to distribute its product, and chills physicians' willingness to prescribe it." Compl. ¶ 56. Plaintiff cites *Novartis Consumer Health v. Johnson & Johnson*, 290 F.3d 580, 596 (3d Cir. 2002) for the proposition that it need only show that it has a "reasonable" basis for believing that it is "likely to suffer injury." Compl. ¶ 56. In *Novartis*, the court found that plaintiff had experienced *actual loss of market share* and monetary harm, which counted as irreparable. *Id.* at 595-96. By contrast, plaintiff's contention that it faces an unquantified "potential loss of future sales,"—even though FDA has not even sent a warning letter—falls far short of establishing a "real and immediate" threat that FDA will institute an enforcement action against it. *See O'Shea v. Littleton*, 414 U.S. 488, 494 (1974); *see also Babbitt v. United Farm*

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[10] *See also United States v. Allgyer*, No. 11-2651, 2012 U.S. Dist. LEXIS 13257, at 16 n.16 (E.D. Pa. Feb. 2, 2012) (rejecting claim that FDA had illegally sent warning letters, citing FDA's Regulatory Procedures Manual with approval); *Regenerative Sciences v. FDA*, No. 09-411, 2010 WL 1258010 (D. Colo. Mar. 26, 2010)*; Cody Labs., Inc. v. Sebelius*, No. 10-147, 2010 U.S. Dist. LEXIS 80118, 32-33 (D. Wyo. July 26, 2010) ("Courts have consistently held, however, that the issuance of a warning letter by FDA does not constitute final agency action ripe for judicial review . . ."), *aff'd*, 446 Fed. Appx. 964 (10th Cir. 2011); *Perez v. Nidek Co.*, 657 F. Supp. 2d 1156, 1166 (S.D. Cal. 2009) (FDA Warning Letters "do not constitute a final decision by the FDA") (citing *Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996)); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 946 (E.D. Wis. 2008) (FDA letters expressing opinion of officials who wrote letter that defendants' products were misbranded were not final agency actions); *Clinical Reference Lab., Inc. v. Sullivan*, 791 F. Supp. 1499, 1504 (D. Kan. 1992) ("Such letters do not bind the agency to the views expressed in them."), *aff'd in part, rev'd in part on other grounds*, 21 F.3d 1026 (10th Cir. 1994); *Estee Lauder*, 727 F. Supp. 1 (dismissing action challenging FDA regulatory letters as unripe because letters stating that certain cosmetics were drugs based on manufacturers' claims were not final agency actions) (citing *Public Citizen Health Research v. FDA*, 740 F.2d 21 (D.C. Cir. 1984)).

Workers Nat'l Union, 442 U.S. 289, 298 (1979) (requiring a plaintiff to show that "the injury is certainly impending") (citation and quotation marks omitted); *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1 (D.D.C. 1989); *Regenerative Sciences, Inc. v. FDA*, No. 09-411, 2010 WL 1258010, at *8 (D. Colo. Mar. 26, 2010) (rejecting claim of hardship based on Warning Letter, stating that "[t]he fact remains that [the plaintiff] has not shown any specific concrete action taken by the FDA that has harmed it or any specific losses it has suffered as a result of FDA action. Therefore, the Court concludes that [the plaintiff's] risk of future FDA enforcement actions is too speculative to warrant judicial intervention . . . .").

B. Plaintiff's Claims Are Not Ripe

Plaintiff is also not entitled to judicial review because its claims are not ripe for adjudication. As the Supreme Court explained in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148 (1967), "injunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these arise in the context of a controversy 'ripe' for judicial resolution." The purpose of the ripeness doctrine is "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Id.* at 148-49.

To determine whether an agency decision is ripe for review, courts examine "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 149. The fitness prong, in turn, depends upon (a) whether the claims raise purely legal questions, and (b) whether the challenge involves final agency action. *Id.* In evaluating the fitness of an issue for judicial review, courts consider whether the issue is "purely legal" and the agency action is final, or, on the other hand, whether "the courts would benefit

from further factual development of the issues presented." *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998). A court must stay its hand when "judicial intervention would inappropriately interfere with further administrative action." *Id.* at 733.

Plaintiff's complaint fails to satisfy the ripeness criteria. As explained above, FDA has not taken any final agency action relating to plaintiff's product at this point in time. *See* Section I.A., *supra*. Plaintiff now asks this Court to step into the shoes of FDA, interpret the relevant statutory and regulatory provisions, and apply them to plaintiff's product. This would displace the agency's primary jurisdiction to determine in the first instance whether plaintiff's product may be legally offered for sale as a medical food. FDA, not this Court, is in the best position to interpret the relevant statute in view of other related provisions within the FDCA and apply its scientific expertise to determine whether a product meets the definition of a medical food, and whether an enforcement action may be appropriate if it does not.

Plaintiff's claims are also unripe because, in addition to the unresolved question whether plaintiff's product is a "medical food," FDA has not considered whether the ingredients in plaintiff's product are even lawful. *See* 21 U.S.C. § 342(a). Further, plaintiff's product (as it is described to this Court) is co-packaged with ibuprofen tablets, although elsewhere plaintiff describes its product as copackaged with an unidentified anti-acne topical gel.[11] FDA has issued at least one warning letter determining that a product offered for sale as a medical food and co-packaged with a drug was a drug.[12] Thus, it is possible that plaintiff's product would not qualify as a medical food on this basis as well. Because the facts are unclear, and FDA's position on

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[11] *See* http://www.prastera.com.

[12] *See* FDA Warning Letter to Physician Therapeutics, L.L.C. (Apr. 8, 2010), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm208680.htm (finding that a therafeldamine (piroxicam 20 mg and theramine) copackaged product was considered to be a drug).

these various issues has not "crystallized," as it would be in the context of an actual enforcement action (or a decision after reviewing an NDA), plaintiff's claims are manifestly premature.

Nor has plaintiff demonstrated that withholding judicial review now will cause it hardship. "[I]n order for the parties' hardship to be sufficient to overcome prudential interests in deferral, that hardship must be both immediate and significant." *Felmeister v. Office of Attorney Ethics, Div. of New Jersey Administrative Office of Courts*, 856 F.2d 529, 537 (3d Cir. 1988). Here, however, plaintiff claims only that it may have "potential loss of future sales," and concedes that, despite an alleged verbal warning, FDA has taken no enforcement action in nearly a year. *Cf. Estee Lauder*, 727 F. Supp. at 5 (regulatory letter warning that FDA was "prepared" to take regulatory action imposed hardship "no greater than any company confronted by an interpretation of a law it dislikes"). Plaintiff will not suffer any hardship if judicial review is postponed until such time as FDA may take concrete action against it or its product.

Even though plaintiff has chosen not to avail itself of formal processes that would result in final agency action, *see* Section III.D.2., *infra*, plaintiff will not suffer hardship because plaintiff would obtain meaningful review in the event that FDA actually brings an enforcement action in the future. Then, and only then, will FDA have gathered the necessary evidence, analyzed the relevant facts, and made the requisite administrative determinations to permit meaningful judicial review. But because formal procedures for rendering a premarket decision about plaintiff's product do not exist, and FDA may never bring an enforcement action, plaintiff's claim of any hardship "is not ripe for adjudication" because "it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *See Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation marks omitted).

C. FDA Enforcement Action May Not Be Enjoined

Not only does plaintiff lack jurisdiction to bring this suit, but the relief plaintiff seeks runs afoul of well-established Supreme Court and appellate precedent. Plaintiff seeks to preemptively enjoin FDA from taking future enforcement action against its product. Compl. at 20 (prayer for relief). Such preenforcement challenges are foreclosed by the Supreme Court's holding in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), wherein the plaintiff sought judicial review of FDA's determination that there was probable cause to believe that the plaintiff's products violated the FDCA, a necessary prerequisite to the government initiating a seizure of the products. The Supreme Court ruled that the district courted lacked jurisdiction to review FDA's pre-seizure probable cause determination because "[j]udicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the [FDCA]" envisioned by Congress in enacting the statute. *Id.* at 600-01 (observing that the plaintiff would have ample opportunity to litigate any constitutional, statutory, or factual claims in the enforcement action itself).

The Supreme Court reaffirmed the *Ewing* principle in *Abbott Laboratories v. Gardner*, calling it "clearly correct." *Abbott*, 387 U.S. at 147. As the Court observed, the "manufacturer in *Ewing* was quite obviously seeking an unheard-of form of relief which, if allowed, would have permitted interference in the early stages of an administrative determination as to specific facts, and would have prevented the regular operation of the seizure procedures established by the [FDCA]." *Id.* at 148. The rule articulated in *Ewing* has been "consistently and strictly observed" by the lower courts, which have held that the decision "precludes judicial interference with the FDA's decision to institute enforcement actions, whatever the precise context." *United States v.*

Alcon Labs., 636 F.2d 876, 881-82 (1st Cir. 1981).[13]

If and when FDA decides that future enforcement action is warranted because of FDCA violations, it has the discretion to initiate a seizure or injunction. *See* 21 U.S.C. §§ 332, 334. Should FDA initiate an enforcement action in the future, plaintiff would have a full opportunity to raise and litigate the claims that it advances here. Then, and only then, may such claims properly be heard.

D. Plaintiff Has Failed To State a Valid Claim Under the APA

Plaintiff has failed to plead a valid cause of action. *See United States v. Nordic Village, Inc.*, 503 U.S. 30, 34 (1992)) ("Where the United States is the defendant . . . federal subject matter jurisdiction is not enough; there must also be a statutory cause of action through which Congress has waived sovereign immunity.").[14] The only statute capable of providing the requisite waiver of sovereign immunity for plaintiff's claims is the APA, 5 U.S.C. §§ 701-706. Section 702 of title 5 waives sovereign immunity for certain suits seeking to obtain judicial review of agency action (or, in some cases, inaction), but, like all waivers of sovereign immunity, it must "be strictly construed, in terms of its scope, in favor of the sovereign." *Dep't*

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[13] *See also Se. Minerals, Inc. v. Harris*, 622 F.2d 758, 764 n.10 (5th Cir. 1980) (explaining that *Ewing* "expresses a total and complete proscription of the district court's power both to undertake a pre-enforcement review . . . and to enjoin federal officials from . . . seizing products or initiating enforcement proceedings under the [FDCA]"); *Pharmadyne Labs., Inc. v. Kennedy*, 596 F.2d 568 (3d Cir. 1979) (affirming dismissal of injunction on *Ewing* grounds); *Parke, Davis & Co. v. Califano*, 564 F.2d 1200, 1205-06 (6th Cir. 1977) (reversing, on *Ewing* grounds, a district court's injunction against FDA); *Rockwell Int'l Corp. v. United States*, 723 F. Supp. 176, 178 (D.D.C. 1989) (stating that the proceedings were still in "flux" and were thus "inappropriate subjects for judicial intervention," following *Ewing*).

[14] The general federal question statute, 28 U.S.C. § 1331, does not waive the government's sovereign immunity. *Swan v. Clinton*, 100 F.3d 973, 981 (D.C. Cir. 1996). 28 U.S.C. § 1346 narrowly waives sovereign immunity only for certain tax refund cases and claims for money damages. Likewise, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, is not an independent basis for subject matter jurisdiction or a waiver of sovereign immunity. *C&E Serv., Inc. v. D.C. Water & Sewer Auth.*, 310 F.3d 197, 201 (D.C. Cir. 2002) (citing cases).

of Army v. Blue Fox, Inc., 525 U.S. 255, 261 (1999). As shown below, even if this Court had jurisdiction to review plaintiff's claims and generously construed those claims as falling within the ambit of the APA, plaintiff has still failed to sustain a valid action under the APA.

1. Plaintiff Has No Claim Because FDA Has Not Taken Final Agency Action

Plaintiff has failed to state a valid claim under the APA because even plaintiff recognizes that FDA has not undertaken the final agency action of determining whether plaintiff's product is a medical food. *See Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (holding that, to be final agency action, it must (1) "mark the consummation of the agency's decisionmaking process – it must not be of a merely tentative or interlocutory nature"; and (2) "must be one by which rights or obligations have been determined, or from which legal consequences will flow"). FDA has neither determined the status of plaintiff's product nor affected any of plaintiff's "rights or obligations." Plaintiff can only point to Warning Letters received by *other* manufacturers for products that are distinct in many ways from plaintiff's product—letters that cannot provide the requisite final agency action needed for review under the APA. In *Holistic Candlers*, the D.C. Circuit dismissed plaintiff's claim on that basis alone because an FDA warning letter is not final agency action. 664 F.3d at 946 (noting that the "APA . . . only provides a right to judicial review of 'final agency action for which there is no other adequate remedy in a court.'").

2. Plaintiff Would Have No Valid Claim For Unreasonable Delay

Nor could plaintiff plausibly allege that FDA has unreasonably delayed or unlawfully withheld action on its request for a determination that its product is a medical food. Pl.'s Mem. at 1. Any such claim is without merit because there can be no unreasonable delay where there is no statutory process for premarket review of medical foods and no legal requirement that FDA provide such a determination at all, let alone within a particular timeframe.

The only provision in the APA that provides for judicial relief for agency delay is 5 U.S.C. § 706(1), which gives a reviewing court authority to compel agency action unreasonably delayed. *See, e.g.*, *Biovail Corp. v. FDA*, 448 F. Supp. 2d 154, 160 (D.D.C. 2006) (pursuing a claim of unreasonable delay under Section 706(1)). Such action can only be compelled in circumstances not present here: "A claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required* to take." *See Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63 (2004) (emphasis in original). "The limitation to required agency action rules out judicial direction of even discrete agency action that is not demanded by law." *Id.*; *see also Massie v. HUD*, 620 F.3d 340, 347 (3d Cir. 2010).

By contrast, plaintiff could have filed an NDA and would have benefitted from the more specific performance goal timeframes and processes applicable to that type of application.[15] Moreover, plaintiff could have sought a formal determination of the agency's views by filing a citizen petition under 21 C.F.R. § 10.30, which requires FDA to issue at least a tentative response within 180 days of such a petition, 21 C.F.R. § 10.30(e)(2), and its answer constitutes a final agency decision. 21 C.F.R. § 10.45(d). Plaintiff argues that "FDA has flatly refused to put [its response] into writing," Pl.'s Mem. at 1, but plaintiff has also refused to initiate any process that would require FDA to respond.

Further, should FDA elect to take enforcement action against plaintiff, the timing of such enforcement decisions is "committed to agency discretion by law." *See, e.g.*, *Heckler v. Chaney*, 470 U.S. 821, 829 (1985); *see also Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 543 (1978) ("administrative agencies should be free to fashion their own rules of procedure

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[15] *See* [Prescription Drug User Fee Act] Reauthorization Performance Goals and Procedures for Fiscal Years 2013 Through 2017, *available at* http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.

and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties") (citations and quotations omitted); *Mobil Oil Expl. & Producing Se., Inc. v. United Dist. Cos.*, 498 U.S. 211, 230 (1991) ("An agency enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures and priorities.") (citations omitted).

E. Plaintiff Has Failed To State a Claim Upon Which Relief Can Be Granted

Even if this Court had jurisdiction to hear plaintiff's claim—whether under the APA or otherwise—plaintiff has still failed to state a claim upon which relief can be granted. This is because even though plaintiff's factual allegations are taken as true for purposes of this motion, plaintiff's claim that its product is a "medical food" fails as matter of law. Products such as plaintiff's may be legally offered for sale as a medical food only if they meet the statutory definition of a "medical food." To protect consumers against unsubstantiated labeling claims and to avoid a proliferation of unapproved drug products disguised as medical foods, FDA has narrowly interpreted the definition of medical food.[16] Plaintiff argues in conclusory fashion that its product meets each of the statute's elements and qualifies as a medical food "as a matter of law." Compl. ¶¶ 43-44; Pl.'s Mem. at 13. Plaintiff also erroneously believes that the issue of whether a disease has "distinctive nutritional requirements" is for a physician, and not FDA, to decide. Pl.'s Mem. at 8. Neither assertion has any merit.

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[16] *See, e.g.*, FDA Warning Letter to Nestle Healthcare Nutrition (Dec. 3, 2009) (rejecting medical food claim because "[t]here is no evidence that patients with the medical condition of 'failure to thrive' have distinctive nutritional requirements or unique nutrient needs"), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm194121.htm; FDA Warning Letter to Realm Labs (Apr. 11, 2013) (rejecting claim that patients with neuropathy have distinct requirement for thiamine or limited ability to ingest it), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm351906.htm.

1. DHEA Is Available Through Dietary Modification

The flaws in plaintiff's arguments are exposed by FDA's rulemaking clarifying the statutory definition of medical foods, in which FDA concluded that a food that is intended for the dietary management of a patient with special medically determined nutrient requirements is a medical food only if the dietary management of such requirements *cannot be achieved by the modification of the normal diet alone*. 21 C.F.R. § 101.9(j)(8)(ii) (emphasis added). This means that a medical food may only be intended for a disease or condition with nutrient requirements that cannot be met through the consumption of conventional foods and/or dietary supplements.[17] As noted above, DHEA is widely available as a dietary supplement.

Plaintiff asserts that these other versions of DHEA are not well regulated and may be inferior to its product. Pl.'s Mem. at 5-6.[18] But FDA has no greater assurance that plaintiff's own product has the purity and characteristics that plaintiff asserts. All medical foods and dietary supplements are subject to current good manufacturing practice requirements. 21 C.F.R. pt. 110 (foods); 21 C.F.R. pt. 111 (dietary supplements). In particular, dietary

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[17] *See also* FDA Warning Letter to Ganeden Biotech (Decl. 8, 2006) ("the products do not have any unique impact on the dietary management of those diseases and conditions beyond that which could be achieved by modification of the normal diet alone"), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076208.htm; FDA Warning Letter to Pam American Labs (Nov. 20, 2009) (rejecting medical food claim for folic acid product because nutritional requirements could be met though modification of the normal diet and also readily obtained from dietary supplements), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm191841.htm.

[18] Plaintiff cites three sources in support of this argument. *Id.* Pl.'s Decl. Ex. 8 is a March 2011 FDA press release cautioning consumers to be aware of fraudulent dietary supplements, particularly weight loss products, body building products, and sexually enhancing products. It is not specific to DHEA. Pl.'s Decl. Ex. 14 is a 1998 article finding variability among DHEA content in supplements, but that article was written before FDA imposed current good manufacturing practice requirements for dietary supplements in 2007. *See* 72 Fed. Reg. 34942 (Jun. 25, 2007). Pl.'s Decl. Ex. 15 is a 1996 article expressing concerns about self-treatment with DHEA and product quality, but this was also written before dietary supplements were subject to current good manufacturing practice requirements. *Id.*

supplement manufacturers must comply with specific requirements for production and process controls to ensure quality. 21 C.F.R. Part 111 Subpart F. Plaintiff's self-serving claim that its competitors' products are inferior and that their availability should be ignored for purposes of deciding whether its product is a medical food has no basis, and directly contravenes FDA's regulation at 21 C.F.R. § 101.9(j)(8)(ii).

2. FDA Has Delegated Authority To Determine What Products Are Medical Foods

In addition, FDA interprets the governing statute as requiring a strong showing that the disease or condition needs "specific dietary management" and has "distinctive nutritional requirements, based on recognized scientific principles[ ] established by medical evaluation." 21 U.S.C. § 360ee(b)(3). Absent these and other limitations, the statute would create a gaping regulatory loophole by allowing manufacturers to offer their products for sale as medical foods for the dietary management of specific diseases or conditions without ever having to demonstrate generally that the disease or condition had a distinctive nutritional requirement in the first instance. Physicians, rather than being able to rely on labeling statements, would have to constantly second-guess them to provide appropriate patient care.

Plaintiff's preferred scheme would supplant FDA's jurisdiction to determine whether a product is a "medical food," and instead make the entire regulatory system turn on whether individual physicians agree with the manufacturer's labeling claims. If each individual physician made such a determination, there would be no regulatory system at all. The statute does not contemplate such a free-for-all. *See Mohamad v. Palestinian Auth.*, __ U.S. __, 132 S. Ct. 1702, 1707 (2012) (reading statute in view of context and to avoid an absurd result "Congress could not plausibly have intended"). This interpretation also ignores how labeling works: physicians rely on labeling claims when making treatment decisions: "The need for physicians and patients

to have confidence that any claim that a product is a medical food formulated for the specific dietary management of a disease or condition requires that a strong standard of substantiation be in place." 61 Fed. Reg. 60666-67. The statute contemplates that the physician has a patient-specific confirmatory role, but does not turn the physician into a regulator.

FDA is unaware of any other instance in which a provision of the FDCA has been interpreted to allow for such potentially arbitrary regulation, in which doctors who unwittingly believe labeling claims (or go the extra mile to attempt to independently verify them) would provide the requisite imprimatur so that a manufacturer could legally offer its product for sale as a medical food, but such a product would not qualify if an individual doctor were more skeptical. Plaintiff even concedes that patients' medical records are not publicly available, and thus that there would be no basis to verify whether a physician has made the requisite judgment to qualify a product as a medical food. Pl.'s Mem. at 10. Thus, it is not even clear that plaintiff's own product would qualify as a medical food, even if plaintiff's interpretation of the statute were correct. Moreover, and more fundamentally, because medical foods are not prohibited by federal law from being dispensed without a prescription,[19] consumers could conceivably buy plaintiff's product without any physician oversight, and without any independent assurance (from FDA or a physician) that the labeling claims were correct.

FDA has been delegated authority to interpret its organic statute, and to decide whether a product is a medical food and whether a disease or condition needs specific dietary management and has distinctive nutritional requirements. *See* 21 U.S.C. § 371(a) (granting FDA general authority to issue binding, substantive regulations). FDA's interpretation of the statute must be

[19] The requirement for a prescription in 21 U.S.C. § 353(b) and 21 C.F.R. § 201.100 only applies to dispensing drug products, not medical foods.

upheld if reasonable. *See Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 983 (2005) ("[A]mbiguities in statutes within an agency's jurisdiction to administer are delegations of authority to the agency to fill the statutory gap in reasonable fashion. Filling these gaps . . . involves difficult policy choices that agencies are better equipped to make than courts."); *Sw. Pa. Growth Alliance v. Browner*, 121 F.3d 106, 117 (3d Cir. 1997) (noting that courts owe deference to "factual determinations within an agency's area of special expertise"). Plaintiff's contrary interpretation, which only serves to benefit itself, would upend the complex, interrelated regime governing drug approvals, dietary supplements, and medical foods. Its interpretation is not grounded in reality or common sense, and should be soundly rejected.

3. Plaintiff's Allegations Do Not Establish That Its Product Is a Medical Food as a Matter of Law

Although FDA has not formally considered whether lupus may have distinctive nutritional requirements, it has serious reservations about plaintiff's assertion that there are such requirements for purposes of the medical food statute. Even if plaintiff were correct that lupus patients may benefit from DHEA, plaintiff has not shown that lupus results in a "distinctive nutritional requirement" for DHEA, as required by 21 U.S.C. § 360ee(b)(3).[20] Whether the

[20] The studies plaintiff cites do not qualify its product as a medical food as a matter of law. Plaintiff cites a 1987 study showing decreased levels of different androgens in women with lupus, including DHEA, but such low levels do not necessarily mean the low levels (of DHEA) would qualify as a "distinctive nutritional requirement," or that lupus is subject to dietary management with DHEA. Pl.'s Dec. Ex. 4 at 244. Plaintiff also cites clinical studies purporting to show that DHEA may reduce the frequency and severity of lupus autoimmune flares. Pl.'s Dec. Ex. 9-11. Each of these studies appears to have evaluated the potential for DHEA to *treat* lupus, and did not consider whether it is a distinctive nutritional requirement. *See, e.g.*, Ex. 10 at 2924 ("The present study was designed to evaluate the safety and efficacy of DHEA in treatment of female patients with mild-to-moderate [lupus] disease activity."); Ex. 11 at 2858 ("*Objective.* To determine whether prasterone administration results in improvement or stabilization of systemic lupus [] disease activity and its symptoms."). Even plaintiff's own website is equivocal on whether DHEA is a requirement for lupus patients: "When your body lacks sufficient prasterone, your body *may not* be able to make the estrogen and testosterone your body

symptoms of a disease or condition are mitigated through the use of a certain substance is not relevant to whether that disease or condition has a "distinctive nutritional requirement" that can be managed with a medical food. Plaintiff ignores that a medical food must be intended for the *dietary management* of a disease or condition. 21 C.F.R. § 101.9(j)(8)(ii). By contrast, a product intended to cure, mitigate, or treat a disease is a drug. 21 U.S.C. § 321(g)(1)(B).

In addition, DHEA is not an approved food additive or otherwise subject to a statutory exemption from the food additive requirements of the FDCA. *See* 21 U.S.C. §§ 321(s), 348(a).[21] Nor is FDA aware of any basis for the general recognition of safety based either on scientific procedures or common use in food prior to January 1, 1958. *See id.* Unapproved food additives are "presumed unsafe" and a food containing an unapproved food additive is adulterated. 21 U.S.C. § 348(a); 21 U.S.C. § 342(a)(2)(C).[22] Finally, plaintiff's labeling raises the question whether its combination packaging with ibuprofen or anti-acne gel may render it a drug. Pl.'s Decl. Ex. 17. FDA has not finally considered any of these matters for plaintiff's product, each of which independently precludes it from being declared a "medical food" as a matter of law.

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needs. This is important because estrogen and testosterone *may* be essential for your immune system to function properly." *See* http://www. prasterone.com.

[21] *See* Guidance for Industry: Frequently Asked Questions About Medical Foods (Rev. May 2007), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/MedicalFoods/ucm054048.htm.

[22] Plaintiff asserts that its product is "safe," citing its exhibits 13 and 25. Pl.'s Mem. at 16. Exhibit 13 is a presentation given by a sponsor for NDA 21239, which sought approval of DHEA to treat lupus. FDA has never approved that product as safe and effective. Exhibit 25 is an FDA review of NDA 21239, which concludes: "In general the epidemiologic studies reviewed in this report have many limitations. Temporal precedence bias, small size, inability to control for confounding variables, and the method of DHEA measurement are among the most common limitations of studies reviewed in this report. *No meaningful conclusion about the association of exogenously administered DHEA and cancer risk can be made* based on these epidemiologic studies of endogenous levels of DHEA." *Id.* at 6 (emphasis added). Neither of these exhibits establishes that plaintiff's DHEA product is generally recognized as safe. *See* 21 C.F.R. § 170.30.

IV. Plaintiff's Motion for a Preliminary Injunction Should Be Denied

Preliminary injunctive relief is an "extraordinary" remedy that "may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. NRDC, Inc.*, 555 U.S. 7, 22 (2008); *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008). To qualify for preliminary injunctive relief, a party must demonstrate "(1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief." *Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004). While all four elements are essential, the Third Circuit has held that a court may not grant injunctive relief, "regardless of what the equities seem to require," unless the movant carries its burden of establishing both a likelihood of success and irreparable harm. *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484 (3d Cir. 2000). "[T]he grant of injunctive relief is an 'extraordinary remedy, which should be granted only in limited circumstances.'" *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 800 (3d Cir. 1989) (quoting *Frank's GMC Truck Ctr. Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 102 (3d Cir. 1988)).

A. Plaintiff Is Not Likely To Succeed On the Merits

Plaintiff has no likelihood of success on the merits because, as demonstrated above, its Complaint is subject to dismissal in its entirety due to lack of jurisdiction and for failing to state a claim upon which relief can be granted. Plaintiff seeks an injunction to "[t]emporarily enjoin FDA from commencing enforcement action against Plaintiff and its product until the Court issues a Declaratory Judgment." Pl.'s Mem. at 18. But for all of the reasons described above, plaintiff's claim that this Court should usurp FDA's role to interpret and apply the medical food statute has no merit, and should be dismissed outright. Because plaintiff cannot establish any

likelihood of eventual success on the merits of its claims, this Court should deny plaintiff's request for extraordinary, emergency relief. *See Munaf*, 553 U.S. at 689-90.

B. Plaintiff Has Not Established It Will Suffer Irreparable Harm in the Absence of Preliminary Injunctive Relief

Plaintiff has also failed to demonstrate that it will suffer irreparable harm absent injunctive relief or that the balance of hardships tips in its favor. Courts insist that only irreparable harm that is likely justifies the issuance of a preliminary injunction. *Winter*, 555 U.S. at 22. Nor is a mere "possibility" of irreparable harm sufficient to justify such relief:

> Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction. … Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.

Winter, 555 U.S. at 22-23 (citations omitted, emphasis in original).

Moreover, a preliminary injunction is not appropriate where the harm is speculative and contingent upon future events. *See, e.g., O'Shea v. Littleton*, 414 U.S. 488, 493-495 (1974). "It must be alleged that the plaintiff 'has sustained or is immediately in danger of sustaining some direct injury' as the result of the challenged statute or official conduct." *Id*. at 494 (quoting *Massachusetts v. Mellon*, 262 U.S. 447, 488 (1923)); *Hohe v. Casey*, 868 F.2d 69, 72 (3d Cir. 1989) (plaintiff has the burden of proving a "clear showing of immediate irreparable injury").

Plaintiff does not come close to satisfying this standard. Plaintiff contends that FDA's alleged "verbal threat chills Plaintiff's willingness to market its product, distributors' willingness to distribute it and physicians' willingness to prescribe it." Pl.'s Mem. at 14. Plaintiff does not quantify any harm, but rather speculates that its harm is a "potential loss of future sales and market share," which it characterizes as "irreparable harm" as a matter of law. *Id*. Plaintiff cites *Novartis Consumer Health*, but in that case the court affirmed a finding of irreparable harm

because of a showing of a *present* injury to market share. 290 F.3d at 595-96. It did not hold that any speculative potential future losses necessary qualify as irreparable harm, a result foreclosed by *Winter*, which requires more than a possibility of injury. This Circuit has cited with approval "well-settled law that injunctions will not be issued merely to allay the fears and apprehensions or to soothe the anxieties of the parties." *Cont'l Group, Inc. v. Amoco Chems. Corp.*, 614 F.2d 351, 359 (3d Cir. 1980) (internal citations omitted).

Plaintiff points out that FDA has not acted for nearly a year (Pl.'s Mem.at 13), and plaintiff has not even received a warning letter for its product. Given that FDA has not taken any enforcement action against any of the medical food manufacturers who have actually received warning letters, any claim that FDA will imminently take action against plaintiff is highly speculative. For all of these reasons, plaintiff cannot meet its burden of establishing that it will suffer irreparable injury in the absence of preliminary injunctive relief.

C. The Balance of Harms and the Public Interest Weigh Against the Entry of Preliminary Injunctive Relief

The balance of harms also weighs against an injunction because plaintiff's desire for a more certain regulatory landscape in which to offer its product for sale does not outweigh FDA's interest in its exercise of enforcement discretion and the timing of its regulatory decisionmaking without judicial interference. *See, e.g., Mobil Oil*, 498 U.S. at 230 ("An agency enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures and priorities."). Moreover, it is certainly not in the public interest to waste judicial resources adjudicating unripe disputes. *See Abbott Labs.*, 387 U.S. at 148. Plaintiff touts its product as a cure for lupus, asserting that a court order would save four women's lives every day. Pl.'s Mem. at 18. While it is certainly in the public interest to save lives, plaintiff has not demonstrated that its product is capable of doing so, nor has it demonstrated that it should be given a judicial green

light to offer its product for sale to patients who might be misled by unsubstantiated labeling claims.

CONCLUSION

For the foregoing reasons, plaintiff's Complaint should be dismissed with prejudice and its motion for a preliminary injunction should be denied.

Dated: July 22, 2013

Respectfully submitted,

/s/ Roger Gural

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that he is an employee in the United States Department of Justice and is a person of such age and discretion as to be competent to serve papers.

On this date the undersigned caused to be sent via CM/ECF, a copy of MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION, addressed to:

J. Mark Pohl, JP4457
PHARMACEUTICAL PATENT ATTORNEYS, LLC
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Counsel for Plaintiff

I declare under penalty of perjury that the foregoing is true and accurate to the best of my knowledge, information and belief.

DATED: July 22, 2013

s/ Roger Gural
ROGER J. GURAL
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